Immunization Update 2010

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Indianapolis, IN May 19 , 2010





Disclosures

- The speaker is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
- The speaker will discuss the off-label use of Hiberix, Prevnar 13, human papillomavirus, zoster, meningococcal conjugate, and zoster vaccines
- The speaker will not discuss vaccines not currently licensed by the Food and Drug Administration





www.cdc.gov/vaccines/recs/schedules/default.htm

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼ Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years	
Hepatitis B ¹	HepB	рВ НерВ			HepB						,	
Rotavirus ²		1	RV	RV	RV ²		·			***************************************	, , , , , , , , , , , , , , , , , , ,	Range of recommended ages for all
Diphtheria, Tetanus, Pertussis ³		1	DTaP	DTaP	DTaP	see footnote ³	D1	ГаР		***************************************	DTaP	
Haemophilus influenzae type b ⁴		1 1 1 1 1 1	Hib	Hib	Hib ⁴	Hib				, , ,	children except certain high-risk	
Pneumococcal ⁵		1	PCV	PCV	PCV	PCV			PPSV		groups	
Inactivated Poliovirus ⁶		7 7 7 7	IPV	IPV		IPV				IPV		
Influenza ⁷		1						Docom	mond	od Im	muniz	ation Sch
Measles, Mumps, Rubella ⁸								mmended Immunization Scho For those who fall behind or sta				
Varicella ⁹						V	For those who fall bening of s					
Hepatitis A ¹⁰												

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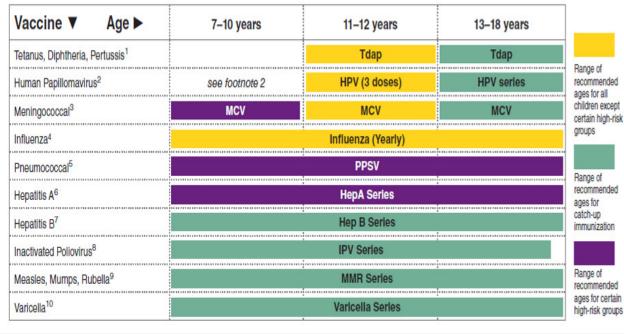
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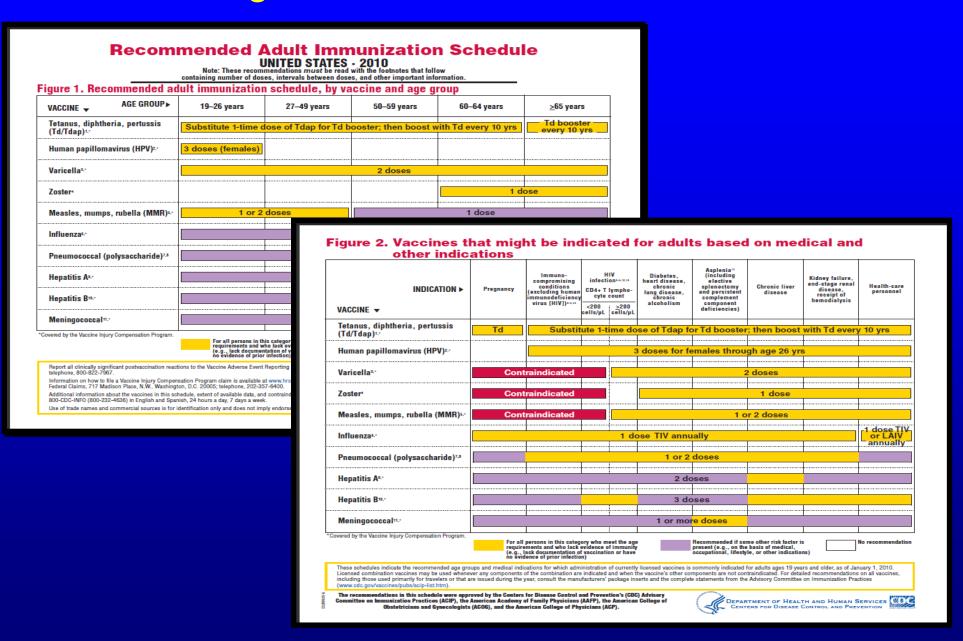
This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory

Meningococcal¹¹

tion Schedule for Persons Aged 7 Through 18 Years—United States • 2010 hind or start late, see the schedule below and the catch-up schedule



www.cdc.gov/vaccines/recs/schedules/default.htm



New Rotavirus Contraindication



- Severe combined immunodeficiency (SCID) has been added as a contraindication to both rotavirus vaccines (Rotarix & Rotateq)
 - 7 confirmed cases of vaccine-type rotavirus infection in infants diagnosed with SCID





FDA Revises Recommendations for Use of Rotavirus Vaccines

www.cdc.gov/vaccines/vpd-vac/rotavirus/default.htm#FDA



- •Based on careful evaluation of a variety of scientific information
- Resume use of Rotarix and continue use of RotaTeq
 - -No evidence that either PCV1 or PCV2 poses a safety risk in humans
 - -Neither is known to cause infection or illness in humans
- Both rotavirus vaccines have strong safety records
 - -Clinical trials involving tens of thousands of patients
 - -Clinical experience with millions of recipients
 - -Benefits of the vaccines are substantial
 - ■Prevention of hospitalization for severe rotavirus disease in the U.S.
 - Death in other parts of the world

Is there any medical follow-up needed for children who have received the Rotarix or RotaTeq vaccine?

FDA does not believe medical follow-up is warranted for children who have been vaccinated with Rotarix and RotaTeg vaccines. Extensive studies, including placeho-controlled, randomized clinical

Haemophilus influenzae type b





Hiberix

- Haemophilus influenza type B vaccine conjugated to tetanus toxoid (PRP-T)
- Approved as a "booster dose" for children 15 months through 4 years of age who have received a primary series of any Hib-containing vaccine
- Supplied as a lyophilized powder that is reconstituted with <u>0.9% saline</u> <u>diluent</u> (provided in a syringe)



www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm

Hiberix

- Can be used as the <u>last dose</u> in the Hib series in a child who has received at least one prior dose of ANY Hibcontaining vaccine
- Should NOT be use as the ONLY Hib dose in a child who has received no prior Hib doses
- Can be used at 12-14 months of age*







Prevnar 13

- February 24, FDA approved Prevnar 13 & ACIP recommends PCV13 to replace PCV7
 - Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, & 23F
 - Indicated for
 - all children 2 through 59 mos of age
 - High-risk children 60-71 mos (chronic illness, immunocompromised, asplenia)
 - Four-dose schedule at 2, 4, 6, and 12-15 mos
 - Contains aluminum adjuvant

www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf

www.cdc.gov/vaccines/recs/provisional/downloads/pcv13-mar-2010-508.pdf







Prevnar 13

- Children who have received 1 or more doses of PCV7 should complete the immunization series with PCV13
- Single supplemental dose of PCV13 following a complete PCV7 series
 - Healthy children 14-59 mos.
 - Children 14-71 mos. with an underlying medical condition (even if already received PPSV23 dose)





Prevnar 13

- Single supplemental dose of PCV13 for children 6-18 years at increased risk for invasive pneumococcal disease*
 - Functional or anatomic asplenia (including sickle cell disease)
 - Immunocompromised (including HIV)
 - Cochlear implant
 - CSF leak





Pneumococcal Polysaccharide Vaccine (PPSV23) ACIP Recommendations

- Adults 65 years and older
- Persons 19-64 years of age who are current cigarette smokers
- Persons 19-64 years of age with asthma
- Persons 2 years and older with
 - chronic illness
 - anatomic or functional asplenia
 - immunocompromised (disease, chemotherapy, steroids)
 - HIV infection
 - environments or settings with increased risk





Polio



New IPV Recommendations

- No change in the recommended IPV schedule of four doses at ages 2 months, 4 months, 6 through 18 months, and 4 through 6 years
- Minimum interval between the next-to-last and last doses is now 6 months (FOR ANY COMPLETE IPV SERIES, <u>REGARDLESS</u> OF AGE)
- Minimum age for the final IPV dose is now 4 years



www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a3.htm? s_cid=mm5830a3_e



New IPV Recommendations

- When 4 (or more) doses of IPV are administered before the 4th birthday, an additional dose of age appropriate IPV should be given on or after the 4th birthday
- In the first 6 months of life, the minimum age and minimum intervals are recommended <u>only</u> if the person is at risk for imminent exposure to circulating poliovirus, such as travel to a polio endemic region or during an outbreak

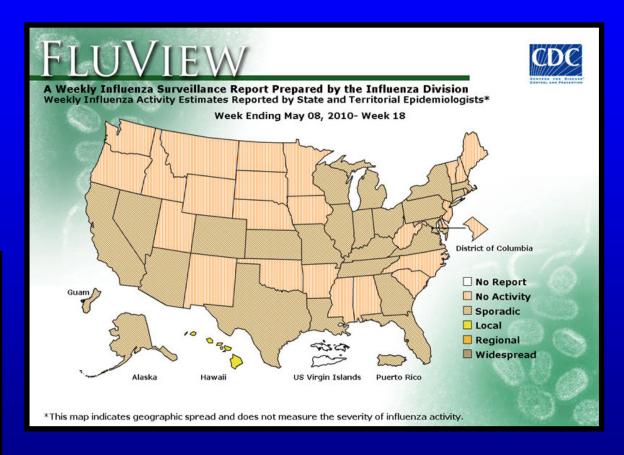




Influenza







www.cdc.gov/h1n1flu





Impact of H1N1 Pandemic Influenza-United States, 2009-2010

- Estimated 60 million persons infected
- Estimated 270,000 2009 H1N1-related hospitalizations
- Estimated 12,270 2009 H1N1-related deaths
 - Approximately 1,270 pediatric deaths
 - Approximately 11,000 deaths in adults
 - Greatest frequency of deaths 50-64 year olds (80% of whom had underlying health conditions)
- Declining activity nationwide, but sporadic activity expected through summer





Influenza Vaccine Strains 2010-2011

- A/California/7/2009 (H1N1)-like virus
- A/Perth/16/2009 (H3N2)-like virus
- B/Brisbane/60/2008-like virus





Influenza Vaccination 2010-2011

 ACIP voted on Feb. 24, 2010 to expand the recommendation for annual influenza vaccination to include all people aged 6 months and older

- The expanded recommendation is to take effect in the 2010-2011 influenza season
- The new recommendation seeks to remove barriers to influenza immunization and signals the importance of preventing influenza across the entire population





http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5916a2.htm

Licensure of a High-Dose Inactivated Influenza Vaccine for Pers Aged ≥65 Years (Fluzone High-Dose) and Guidance for Use ---United States, 2010

Weekly April 30, 2010 / 59(16);485-486

Persons aged ≥65 years are at greater risk for hospitalization and death from seasonal influenza compared other age groups (1,2), and they respond to vaccination with lower antibody titers to influenza hemagglutir established correlate of protection against influenza) compared with younger adults (3). On December 23, 2 the Food and Drug Administration (FDA) licensed an injectable inactivated trivalent influenza vaccine (Fluzor Dose, Sanofi-Pasteur) that contains an increased amount of influenza virus hemagglutinin antigen compare other inactivated influenza vaccines such as Fluzone. Fluzone High-Dose is licensed as a single dose for use persons aged ≥65 years and will be available beginning with the 2010--11 influenza season. The Advisory Committee on Immunization Practices (ACIP) reviewed data from prelicensure clinical trials on the safety an immunogenicity of Fluzone High-Dose and expressed no preference for the new vaccine over other inactivat trivalent influenza vaccines (4). This report summarizes the FDA-approved indications for Fluzone High-Dose provides guidance from ACIP for its use.





Fluzone High-Dose

- A higher dose formulation of TIV (sanofi Pasteur) licensed by FDA on 12/23/2009 for use in people 65 years or older
- Will be available in 2010-11 influenza season
- Contains 4 X the amount of influenza antigen compared to other TIV vaccines
- In one study of people 65 years and older produced higher antibody levels, but slightly higher local reactions
- Studies underway to assess relative effectiveness compared to standard dose. Results will not be available before the 2010-11 influenza season
- ACIP has not expressed a preference for Fluzone High-Dose or any other licensed inactivated influenza vaccine for use in people age 65 and older



New TIV for Adults

- Agriflu (Novartis)
- Licensed by FDA Nov. 27/2009
- Will be available in 2010-11 influenza season
- For use in people 18 years of age and older.





Expanded Age Indications for Two TIV Vaccines

- Afluria (CSL Vaccines) now licensed for use in persons
 6 months of age and older
- Fluarix (GSK Biologicals) now licensed for use in persons 3 years of age and older





Measles and Mumps









Measles outbreak in Metro Vancouver



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Be the



Public warned to be alert after ten confirmed cases in the past two weeks

Article

Comments (45)

Sunny Dhillon

Vancouver, BC — The Canadian Press
Published on Tuesday, Mar. 30, 2010 4:48PM EDT
Last updated on Tuesday, Mar. 30, 2010 5:12PM EDT

The B.C. Centre for Disease Control is warning the public to be alert after a measles outbreak in Metro Vancouver.



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More than 1,000 get mumps in New York, New Jersey since August

February 8, 2010 10:00 p.m. EST



The greater New York City area has seen more than 1,000 cases of mumps since August..

New York (CNN) -- More than 1,000 people in New Jersey and New York, many of them adolescent Orthodox Jews, have been sickened with mumps since August, health authorities said Monday.

Orange County, New York, has confirmed 494 cases since early November, county spokesman Richard Mayfield told CNN.
Almost all of those infected with the virus are of the Orthodox or Hasidic Jewish population, and their average age is 14, he said.

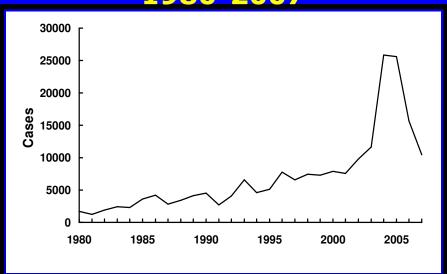
STORY HIGHLIGHTS

 Almost all the cases of mumps involve adolescent Orthodox Jews Neighboring Rockland County has confirmed 317 cases since August, with all of the sick from the Orthodox Jewish community, said Kathleen Henry, county Deputy Commissioner of Health. Their

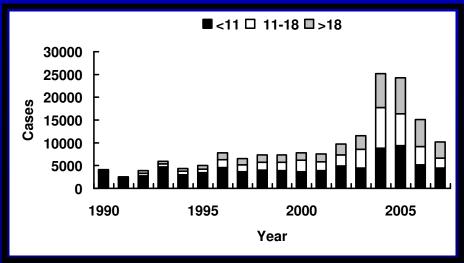
Pertussis in Adults



Pertussis—United States, 1980-2007



Reported Pertussis by Age Group, 1990-2007



"Cocooning" Strategy to Prevent Pertussis Infection in Infants



- Assure that you and other staff in your office or facility have received Tdap
- Partner with clinicians who have access to parents and siblings of infants (e.g., OB-GYN providers, prenatal/new parent educators) to provide Tdap to families of infants
- Vaccinate new mothers at the time of discharge if they have not previously received Tdap



ODC

www.cdc.gov/mmwr/PDF/rr/rr5517.pdf

Tdap Use in Adolescents and Adults

- Tdap approved ages
 - 10 through 64 years for Boostrix



11 through 64 years for Adacel



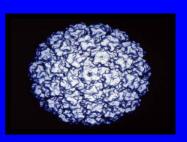
- Tdap not approved for adults 65 years or older
 - Off-label use of Tdap in this age group NOT recommended

Td and Tdap Minimum Intervals

- There is no absolute minimum interval between Td and Tdap
- In "routine" circumstances separate Td and Tdap by at least 5 years to reduce the chance of a local reaction
- If pertussis immunity is imperative (HCP, infant in household) then administer Tdap regardless of interval since last Td







Human Papillomavirus

- HPV2 (GSK, Cervavix)
 - 16 and 18
 - Approved for the prevention of cervical cancers in females



- HPV4 (Merck, Gardasil)
 - 16, 18, 6 and 11
 - Approved for prevention of cervical,
 vaginal & vulvar cancers (in females)
 & genital warts (in females & males)





ACIP Provisional HPV Recommendations for Females

- Routine vaccination of females at 11 or 12 years with 3 doses of HPV vaccine (can begin as young as 9 years)
- Also recommended for females 13 through 26 years who have not been previously vaccinated or who have not completed the full vaccination series

www.cdc.gov/vaccines/recs/provisional/downloads/hpv-vac-dec2009-508.pdf

ACIP Provisional HPV Recommendations for Males

- HPV4 vaccine ONLY may be given to males 9 through 26 years to reduce their likelihood of acquiring genital warts
- Ideally, vaccine should be administered before potential exposure to HPV through sexual contact

www.cdc.gov/vaccines/recs/provisional/downloads/hpv-vac-dec2009-508.pdf



HPV Vaccination Schedule

- Routine schedule is 0, 1- 2*, 6 months
- Third dose should follow the first dose by at least 24 weeks
- An accelerated schedule using minimum intervals is not recommended
- Series does not need to be restarted if the schedule is interrupted
- Whenever possible, the same HPV vaccine product should be used for





HPV Vaccination During Pregnancy

- Initiation of the vaccine series should be delayed until after completion of pregnancy
- If a woman is found to be pregnant after initiating the vaccination series, remaining doses should be delayed until after the pregnancy
- If a vaccine dose has been administered during pregnancy, there is no indication for intervention
- Women vaccinated during pregnancy should be reported to the Merck registry (800.986.8999)







Meningococcal Disease

• Meningococcal polysaccharide vaccine (MPSV4, Menommune)

- 2 years of age and older
- subcutaneous injection
- Meningococcal conjugate vaccine (MCV4, Menactra)

Meningococcal

Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Meningococcal (Groups A, C

- 2 through 55 years of age
- intramuscular injection





MCV4 Revaccination Recommendations

- Children through age 18 years who received their first dose of MCV4 or MPSV4 at ages 2 through 6 years and remain at increased risk for meningococcal disease should receive an additional dose of MCV4 3 years after their first dose*
- Revaccinate every 5 years if still at increased risk





MCV4 Revaccination Recommendations

- Persons through age 55 years who received a dose of MCV4 or MPSV4 after age 6 years and remain at increased risk for meningococcal disease should receive an additional dose of MCV4 5 years after their previous dose*
- Revaccinate every 5 years if still at high risk
- Age 56 and older, MPSV4 every 5 years if still at high risk





MCV4 Revaccination Recommendations

- High-risk persons who should be revaccinated with MCV4
 - Persistent complement component deficiency
 - Anatomic or functional asplenia
 - Microbiologists working with specimens of N. meningitidis
 - Frequent travelers to or persons living in areas with high rates of meningococcal disease





MCV4 Revaccination Recommendations

- MCV4 revaccination recommendation does NOT apply to children whose only risk factor is living in on-campus housing (i.e., college students living in a dormitory)
- If however received MPSV4 five years or more prior – vaccinate with MCV4





Meningococcal Revaccination

 Meningococcal conjugate vaccine, MCV4 (Menactra), is preferred for revaccination, but MPSV4 (Menomune) is an acceptable substitute for persons with precautions or contraindications to MCV4 vaccine





New Meningococcal Conjugate Vaccine

- Menveo (Novartis)
 - FDA approved on February 19, 2010
 - Neisseria meningitidis serogroups
 (A, C, Y, and W-135)



- Conjugated with Oligosaccharide Diphtheria CRM197 (protein carrier)
- FDA approved for use in people ages 11 through 55 years
- May be used for any person 11-55 years for whom MCV4 is indicated, including revaccination
- Solution that contains serogroups C, Y, and W-135 is used to reconstitute lyophilized powder that contains serogroup A



Shingles (Herpes Zoster)





Zostavax

Administer a single dose to persons 60 yrs of age and older who had chickenpox to reduce the risk of subsequent development of zoster and postherpetic neuralgia

- Contains live varicella vaccine virus in much larger amount (14x) than standard varicella vaccine (Varivax)
- Requires freezer storage AT ALL TIMES





ACIP Recommendations for Zoster Vaccine

- Need for booster dose or doses not known at this time
- A history of herpes zoster should not influence the decision to vaccinate
- It is not necessary to inquire about chickenpox or test for varicella immunity before administering zoster vaccine
- Persons 60 years of age and older can be assumed to be immune (born in U.S. before 1980) regardless of their recollection of chickenpox



CDC

www.cdc.gov/mmwr/PDF/rr/rr5705.pdf

Serologic Testing for Varicella Immunity

- If a person 60 years or older is tested for varicella antibody and found to be negative
 - Administer 2 doses of regular varicella vaccine (not zoster vaccine)
 - Zoster vaccine is not indicated for persons whose immunity is based upon varicella vaccination





Zoster Vaccine Contraindications and Precautions

- Severe allergic reaction to a vaccine component or following a prior dose
- Immunosuppression from any cause
- Pregnancy or planned pregnancy within 4 weeks
- Moderate or severe acute illness
- Recent blood product is NOT a precaution
- Current treatment with antiviral drug against herpesviruses (acyclovir, famciclovir, or valacyclovir)
 - Discontinue use at least 24 hours before zoster vaccination





Revised Zostavax Package Insert

- ZOS and PPSV23 should not be administered concurrently
 - Recommendation based on Merck study that showed the average titer against varicella zoster virus (VZV) was lower in persons who received ZOS and PPSV23 at the same visit compared to persons who received these vaccines 4 weeks apart
 - Clinical relevance of this observation unknown
 - No evidence to indicate antibody titers against VZV are a measure of protection against HZ
 - Results were confounded by unexplained differences across comparison group in the baseline VZV antibody titers
 - PPSV23 antibody levels to serotypes 3,14,19A,22F were assessed and unaffected



Significance of this observation is also unknown



Revised Zostavax Package Insert

- Safety profile of ZOS unaffected by simultaneous administration of PPSV23
- To avoid introducing barriers to patients and providers interested in these two important vaccines, CDC has not changed its recommendation for either vaccine.
- CDC continues to recommend that ZOS and PPSV23 be administered at the same visit if the person is eligible for both vaccines*











Hepatitis A

 Two doses at least 6 calendar months apart for all household contacts and other close personal contacts (e.g. regular babysitters) of international adoptees from countries with high or intermediate Hep A endemicity

www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a 4.htm?s_cid=mm5836a4_e





Healthcare Personnel

Need the following immunizations:

- Annual influenza
- Tdap or Td
- Hepatitis B (exposure risk)

Validate immunity status of:

- Varicella
- Measles, Mumps & Rubella (MMR)





Are YOU up to date?



Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

- Appropriate vaccination against measles, mumps, and rubella
 - 2 doses of measles and mumps vaccine
 - at least 1 dose of rubella vaccine, or
- Laboratory evidence of immunity, or
- Laboratory confirmation of disease
- Physician-diagnosed disease no longer recommended as evidence of measles or mumps immunity





Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

 For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should consider vaccinating personnel with two doses of MMR vaccine at the appropriate interval for measles and mumps, and one dose of MMR vaccine for rubella, respectively





Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

For unvaccinated personnel born before 1957 who
lack laboratory evidence of measles, mumps and/or
rubella immunity or laboratory confirmation of disease,
healthcare facilities should recommend two doses of
MMR vaccine during an outbreak of measles or
mumps and one dose during an outbreak of rubella





Be Prepared to Administer Vaccines Correctly



- Ensure staff is adequately trained
- Provide current immunization education

- Adhere to OSHA guidelines for employee safety
- Provide staff with easy to use resources and guidelines
- Document immunizations correctly













For obese, vaccine needle size matters



Frederik Joelving

Mon Feb 8, 2010 10:57am EST

Related News

Alternative prostate cancer vaccine shows promise Mon, Jan 25 2010

NEW YORK (Reuters Health) - Our ever-expanding waistlines may have outgrown the doctor's needle, researchers say, in what could be another casualty of the obesity epidemic.

HEALTH

In a new study, the researchers report that using a standard 1-inch needle to immunize obese





Syncope Following Vaccination

- An increase in the number of reports of syncope has been detected by the Vaccine Adverse Event Reporting System (VAERS)
- 11-18 year old females have contributed most of the increase
- Serious injuries have resulted

www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm?s_cid=mm5717a2_e

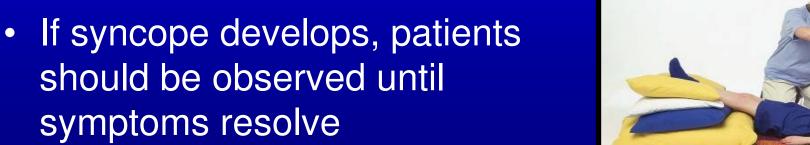




Administer Immunizations SAFELY!

- Have patients seated for vaccination
- Strongly consider observing patients for 15 minutes after they are vaccinated
- should be observed until symptoms resolve









Vaccine Information Statements

Vaccine-Related Topics

- > Immunization Schedules
- Recommendations and Guidelines
- Vaccines & Preventable
 Diseases
- Basics and Common Questions
- > Vaccination Records
- Vaccine Safety and Adverse Events
- > For Travelers
- For Specific Groups of People
- Campaign Materials

Additional Resources

> Publications

Publications:

Vaccine Information Statements

At a glance:

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. <u>Federal law</u> requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Downloadable VISs:

Multiple Vaccines (DTaP, IPV, Hib, PCV, Hepatitis B, and Rotavirus)

Anthrax UPDATED | DTaP | Hepatitis | Hib | Influenza | HPV UPDATED | JE UPDATED | MMR | Meningococcal | PCV13 and PCV7 UPDATED | PPSV23 | Polio | Rabies | Rotavirus UPDATED | Shingles | Smallpox | Td/Tdap | Typhoid | Varicella | Yellow Fever

VIS News Information about new and upcoming VISs (Last updated 5/5/10)

- Printer-friendly version
- Get email updates
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- Glossary / Acronyms
- * Site Map

Quick Links

> More Publications

Related Pages

- >Multi-Vaccine VIS Q&As
- Download a VIS onto a
 Mobile Device
- > Fact Sheet for Vaccine Information Statements
- >FAQs about VISs
- > Myth Exposed!





Immunization Websites for Nurses

Contact Us

Add Me To Your Mailing List

booth during the

Conference

Be sure to visit NNINA's

booth during the 44th

National Immunization

Conference, April 19-22

in Atlanta Georgia, Click

on "News" for more

www.anaimmunize.org/

www.nnina.org/





The National Network of Immunization Nurses & Associates (NNINA)

NNINA is looking for "a few good nurses" and others interested in immunizations to help provide a network of support and expertise in order to advance immunizations in nursing practice.

What does NNINA do?

NNINA provides a collective voice of advocacy and support for nurses and others working in immunizations activities.

NNINA serves as a source of expertise and a clearinghouse for information on vaccine preventable diseases and their prevention and control.



CDC Vaccines and Immunization Contact Information

Telephone 800.CDC.INFO

(for patients and parents)

• Email (for providers)

nipinfo@cdc.gov

Website

www.cdc.gov/vaccines/

Vaccine Safety



www.cdc.gov/od/science/iso/



DEPARTMENT OF HEALTH AND HUMAN SERVICES